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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/676,376    09/29/00    BAICHWAL

A    540.1040

HM22/1003  
DAVIDSON, DAVIDSON & KAPPEL, LLC  
14TH FLOOR  
485 SEVENTH AVENUE  
NEW YORK NY 10036

EXAMINER

WARE, T

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

10/03/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Applicati n No.

09/676,376

Applicant(s)

BAICHWAL ET AL.

Examin r

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

Receipt of declaration and fee file 1-22-01 is acknowledged.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6-9, 13, 21-25, 32-44, 61-64 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Baichwal et al (5,399,359; hereafter '359).

'359 discloses oxybutynin xanthan gum/locust bean gum sustained release compositions comprising a pH modifying agent such as sodium carbonate or sodium bicarbonate. The compositions provide sustained release at least about 24 hours and are in ratios within the instant ranges. See Abstract; C 3, L 24- C 5, L 13; Examples; Claims.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-13, 17, 21-25, 32-44, 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (5,399,359; hereafter '359).

'359 teaches oxybutynin xanthan gum/locust bean gum sustained release compositions comprising a pH modifying agent such as sodium carbonate or sodium bicarbonate. The compositions provide sustained release at least about 24 hours and are in ratios within the instant ranges. Manipulation of the amounts of ingredients such as the pH modifying agent would have been obvious to one skilled in the art at the time of the invention to increase or decrease the degree of cross-linking of the polysaccharides. See Abstract; C 3, L 24- C 5, L 13; Examples; Claims.

5. Claims 1-13, 18-32-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (5,399,359; hereafter '359) in view of Baichwal et al (5,478,574; hereafter '574).

'359 is relied upon for all that it teaches as stated previously. '359 does not teach inclusion of a surfactant in the xanthan gum/locust bean gum compositions.

'574 teaches inclusion of a surfactant in xanthan gum/locust bean gum compositions provides a bimodal or multi-phase controlled release of a therapeutically active ingredient. '574 also teaches that such xanthan gum/locust bean gum compositions are effective for delivering active agents such as diltiazem.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '359 and '574 to achieve a bimodal or multi-phase controlled release of a therapeutically active ingredient.

6. Claims 1-17, 21-25, 32-44, 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (5,399,359; hereafter '359) in view of Panoz et al (4,726,951; hereafter '951).

'359 is relied upon for all that it teaches as stated previously. '359 does not teach the limitation where the pH modifying agent is an organic acid.

'951 is relied upon for teaching inclusion of organic acids in pharmaceutical compositions to modify pH and maintain optimum absorption conditions for an active agent.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '359 and '951 to maintain optimum absorption conditions for an active agent.

7. Claims 1-17, 21-25, 32-44, 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (5,399,359; hereafter '359) in view of over Baichwal et al (WO 97/26865; hereafter '865).

'359 is relied upon for all that it teaches as stated previously. '359 does not teach the limitation where the pH modifying agent is an organic acid.

'865 is relied upon for teaching inclusion of organic acids in xanthan gum/locust bean gum compositions as strength enhancing agents. '865 does not explicitly teach combining two strength enhancing agents, however it would have been obvious to one

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skilled in the art at the time of the invention to do so to provide an additive effect of enhanced strength.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '359 and '865 to achieve an additive effect of enhanced strength.

8. Claims 1-17, 21-25, 32-44, 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (5,399,359; hereafter '359) in combination with Baichwal et al (5,478,574; hereafter '574) and further in combination with Baichwal et al (WO 97/26865; hereafter '865).

'359, '574, and '865 are all relied upon for all that they teach as previously stated. it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of these references to provide sustained release compositions comprising xanthan gum/locust bean gum that is strong and has a bimodal or multi-phase controlled release profile of an active agent.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

tw  
September 27, 2001